

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

May 31, 2016

John Reilly Senior Regulatory Specialist Sterilex Corporation 111 Lake Front Drive Hunt Valley, MD. 21030

Subject: PRIA Label Amendment –Add Additional Organisms to the Product Master Label

Product Name: Sterilex Ultra Powder EPA Registration Number: 63761-5

Application Date: 1/06/16 Decision Number: 512773

Dear Mr. Reilly:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance

Page 2 of 2 EPA Reg. No. 63761-5 Decision No. 512773

with FIFRA section 6. If you have any questions, please contact Jamil Mixon at (703) 308-8032, or via email at mixon.cletis@epa.gov.

Sincerely,

Eric Miederhoff

Product Manager 31

Regulatory Management Branch I Antimicrobials Division (7510P)

Office of Pesticide Programs

Date: May 31, 2016

Enclosure



ACCEPTED

05/31/2016

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No.

63761-5

Sterilex Ultra Powder

[[BASED OFF OF] [BASE D ON] [INCLUDING] [INCLUDES] [USING] [PATENTED PERQUAT® TECHNOLOGY]]

[ONE-STEP DISINFECTANT - CLEANER]

[Federally Inspected Food Processing Facilities], [Federally Inspected Meat And Poultry Plants], [Dairies], [Wineries], [Breweries], [Beverage Manufacturing Facilities], [Dairy Farms], [Swine Farms], [Poultry] [And] [Turkey] Farms], [Farm Premises], [Hatcheries], [Refrigerated Trucks], [Kennels], [Pet Animal Quarters], [Zoos], [Pet Shops], [Animal Laboratories], [Veterinary Facilities], [Animal Care Facilities]

[NON-FOOD CONTACT SURFACE SANITIZER]

[Federally Inspected Food Processing Facilities], [Federally Inspected Meat And Poultry Plants], [Dairies], [Wineries], [Breweries], [Beverage Manufacturing Facilities], [Dairy Farms], [Swine Farms], [Poultry] [And] [Turkey] Farms], [Farm Premises], [Hatcheries], [Refrigerated Trucks], [Kennels], [Pet Animal Quarters], [Zoos], [Pet Shops], [Animal Laboratories], [Veterinary Facilities], [Animal Care Facilities]

[VIRUCIDE[†]]

[Think Pink Once A Week®]

- [Solid Floor Sanitizer]
- [For Use in Dairy, Food, Meat, and Beverage Processing Facilities]
- [Animal Premise Disinfectant, Sanitizer]
- [Solid Footpan Sanitizer]
- [Solid Boot Sanitizer]
- [Floor sanitizing and deodorizing performance]
- [Enhanced traction]
- [Removes* biofilm from dental unit water lines]
- [Prevents and suppresses formation of biofilm in dental unit water lines]
- [Kills biofilm bacteria in dental unit water lines]
- [Maintains dental unit water line effluent water <500 cfu/ml]
- [One-Step Disinfectant Cleaner]
- [Disinfectant]
- [Non-food Contact Surface Sanitizer]
- [Solid Floor Sanitizer]
- [Staphylocidal Pseudomonacidal Salmonellacidal]
- [Use within 8 hours after powder has been dissolved in water]

[* Laboratory studies have shown >90% removal]

Active Ingredients:

N-Alkyl(C ₁₄ 95%,C ₁₂ 3%,C ₁₆ 2%) dimethylbenzylammonium chloride	10.00%
Sodium Carbonate Peroxyhydrate	29.75%
Other Ingredients	60.25%
	100.00%

KEEP OUT OF THE REACH OF CHILDREN **DANGER**

See [back panel] [side panel] [box] for [additional] [first aid] [and] precautionary statement

Manufactured for STERILEX CORPORATION

111 Lake Front Drive Hunt Valley, MD Phone(Toll-Free): 1-800-511-1659 Phone (443) 541-8800 Fax: 410-581-8864

Made in USA		
EPA Reg. No. 63761-5 EPA Est. No		
NET CONTENTS:] (*NOTE TO REVIEWER – this may be printed on container itself) LOT NUMBER:][BATCH NUMBER:] (*NOTE TO REVIEWER – this may be printed on container itself) NOT FOR SALE OR USE AFTER:] Expiration Date][Exp. Date] [Expiry Date]		

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

TREATMENT OF DENTAL UNIT WATER LINES

Important Notice:

Before using Sterilex Ultra please read the following information.

- 1. This product is to be used in conjunction with regular testing of dental unit water.
- 2. The manufacturer of the dental unit should be consulted before use of this product about compatibility of Sterilex Ultra with the dental unit.
- 1. Initial Start-Up Treatment: Treat the Dental Unit Water Lines (DUWL) for three consecutive nights.
- 2. Routine Treatment: Treat DUWL one night/week (Monday-Thursday recommended) after Initial Start-up treatment.

How To Apply Sterilex Ultra Powder:

- 1. At the end of the workday, add eight (8) ounces of **HOT** water to a Sterilex measuring cup or other empty container.
- 2.Add [0.44 ounces (12.5 grams)][one packet] of Sterilex Ultra to the hot water. Use stirrer to mix or swirl to dissolve. Be sure all powder is dissolved. Pour pink liquid into an empty external dental unit water bottle. Do not use PET Bottles (See note for bottle requirements).
- 3. Run Sterilex Ultra mixture through the system until the pink mixture appears at the end of the A/W Syringe and Handpiece Line. Always remove the Handpiece.
- 4. Allow the mixture to sit in the unit overnight (Place the ends of waterlines into a sink or cuspidor in case any pink mixture drips overnight).
- 5. At the beginning of the next workday, discard any remaining mixture in external water bottle. Rinse the external water bottle with hot water.
- 6. Fill the external water bottle with hot water. Flush each line (A/W Syringe, Handpiece) until the bottle is empty.

Note: Do Not Use Thin Walled Polyethylene Terephthalate (PET) Bottles. We Recommend Either A High Density Polyethylene Bottle With A Minimum Thickness Of 0.08 Inches Or A High/Low Density Polyethylene Blend With A Minimum Thickness Of 0.14 Inches.

[NOTE TO REVIEWER: All surfaces listed between the {} brackets are meant to be optional language]

Sterilex Ultra Powder is for use on the following washable hard, nonporous surfaces:

{Medical machines (x-ray, MRIs, CAT scanners), noncritical medical devices and equipment surfaces (that do not penetrate the body or contact the human bloodstream or mucous membranes);}

{Steam sterilizer water reservoirs, steam sterilizer water reservoir tubing;}

{Water reservoir tanks, water reservoir pipes, tanks, and piping systems used in food processing;}

{Floors, walls, countertops, stovetops, sinks, appliances, refrigerators, plastic and other nonporous cutting boards and chopping blocks; coolers, ice chests; non residential refrigerator bins for meat, fruit, vegetable and egg; food processing equipment (k-pac equipment, injectors, slicers, knives, steel mesh gloves, deboners, saws, grinders, cutters, racks, dairy equipment, interlocking belts, outside surfaces of kitchen equipment, beer fermentation and holding tanks, brewery pasteurizers, wine fermentation tanks, beverage dispensing equipment, beverage transfer lines, bottling or premix dispensing equipment), appliances exterior, refrigerators exterior;}

{Drinking water coolers, ice making machines, transfer line tubing, water lines, watering systems, farm animal nipple drinkers;}

{Cabinets, highchairs, garbage cans, garbage storage areas, refrigerated storage and display equipment, tables, picnic tables, outdoor furniture, chairs, desks, telephones, doorknobs, shower stalls, tubs and glazed tiles, whirlpool bathtubs, bathtubs, sinks, urinals, exterior toilet bowl surfaces, other bathroom fixtures;}

{Kennel runs, cages, waterers and feeders, automatic feeders, hauling equipment, dressing plants, loading equipment, farrowing barns and related areas (nursery blocks, creep areas), chutes, feed racks, mangers, troughs, fountains and waterers, forks, shovels, scrapers, barns, pens, stalls, facilities and fixtures occupied or traversed by animals, hatchery areas (egg receiving and holding, setter room, tray dumping, chick holding, processing and loading), trays, buggies, racks, egg flats, trucks, poultry buildings, ceilings, sidewalls and floors, drinkers and other poultry house related equipment; nest pads;}

{Coils and drain pans of air conditioning and refrigeration equipment and heat pumps, conductive flooring;}

{Nonporous salon/barber tools and instruments (combs, brushes, scissors, blades, pedicure and manicure instruments, pedicure and manicure tubs);}

{Hard nonporous surfaces, listed on this label, that are made of metal, stainless steel, glazed porcelain, glazed ceramic, sealed stone, hard fiberglass, plastic (such as polystyrene, polypropylene), glazed porcelain tiling, enameled surfaces, finished/sealed and painted woodwork, finished floors, Formica®, vinyl and plastic upholstery. }

(Sterilex Ultra Powder is for use on washable hard, nonporous surfaces in: hospitals, medical and dental offices, nursing homes, health care facilities, ultrasonic baths (ultrasonic cleaning units), federally inspected food processing facilities, federally inspected meat and poultry plants, wineries, breweries, beverage manufacturing facilities, dairy farms, swine farms, poultry and turkey farms, farm premises, hatcheries, refrigerated trucks, kennels, pet animal quarters, zoos, pet shops, animal laboratories, veterinary facilities, animal care facilities, transportation terminals, hotels and motels, factories, business and office buildings, barber shops, salons, boats, ships, campers, trailers, mobile homes, homes, kitchens, bathrooms, household areas, cars, buses, trains, taxis, airplanes, restaurants, bars, cafeterias, institutional kitchens, food preparation and storage areas, convenience stores, food storage areas, public rest rooms, institutions, schools and colleges, athletic facilities, locker rooms, dressing rooms, shower and bath areas, and exercise equipment.}

PRECLEANING_INSTRUCTIONS (OPTIONAL STEP):

Although **Sterilex Ultra Powder** provides one-step cleaning and disinfection, precleaning may be desired for some areas, articles and surfaces in certain cases. Prepare a precleaning solution by adding 0.16 oz. – 3.36 oz. of **Sterilex Ultra Powder** per 1 gallon of water (or equivalent use dilution), depending on the level of gross filth [soil] to be precleaned. Clean surfaces with precleaning solution by pouring, wiping, brushing, scrubbing, foaming, spraying with a coarse trigger sprayer, sponging, immersing, using a clean in place (CIP) system, pumping it through the system, drawing it through the system or mopping. Rinse all surfaces thoroughly with a potable water rinse.

GENERAL ONE STEP DISINFECTION AND CLEANING DIRECTIONS FOR HARD NON-POROUS SURFACES

Sterilex Ultra Powder is a hospital-use disinfectant at 0.42 - 0.52 lb per gallon (50 - 63 grams per liter), Bactericidal according to the current AOAC Use-Dilution Test Method modified in the presence of 400 ppm hard water plus 5% organic serum against:

[Bacteria:]

[Pseudomonas aeruginosa [Pseudomonas] [ATCC# 15442]] [Staphylococcus aureus [Staph] [ATCC# 6538]] [Salmonella enterica [Salmonella] [ATCC# 10708]] [Salmonella enterica enteritidis [ATCC 13076]] [Campylobacter jejuni [ATCC 29428]]

APPLICATION INSTRUCTIONS:

Remove gross filth [soil] from all areas, articles and surfaces to be disinfected using a pre-clean, pre-flush, or pre-scrape and, if necessary, presoak. Mix 0.42 - 0.52 lbs Sterilex Ultra Powder per gallon of water [50 - 63 grams/liter]. Thoroughly wet surfaces by pouring, wiping, brushing, scrubbing, foaming, spraying with a coarse trigger sprayer, sponging, using a clean in place (CIP) system, pumping it through the system, drawing it through the system or mopping. Allow surfaces to remain wet for at least 10 minutes. Do not breathe spray. Rinse all surfaces thoroughly with a potable water rinse. Use within 8 hours after powder has been dissolved in water.

†VIRUSES

Avian Influenza

Sterilex Ultra Powder is effective against Avian Influenza A on hard, inanimate surfaces in one step at 1.3 – 2 ounces per gallon of water [9.7-15 grams/liter], with a 5 minute contact time in the presence of 400 ppm hard water and organic soil. Remove gross filth [soil] from all areas, articles and surfaces to be disinfected using a pre-clean, pre-flush, or pre-scrape and, if necessary, presoak. Mix 1.3 – 2 ounces Sterilex Ultra Powder per gallon of water [9.7-15 grams/liter]. Thoroughly wet surfaces by pouring, wiping, brushing, scrubbing, foaming, spraying with a coarse trigger sprayer, sponging, using a clean in place (CIP) system, pumping it through the system, drawing it through the system or mopping. Allow surfaces to remain wet for at least 5 minutes. Do not breathe spray. Rinse all surfaces thoroughly with a potable water rinse. Use within 8 hours after powder has been dissolved in water.

Sterilex Ultra Powder is effective against the following viruses on hard, inanimate surfaces in one step at the concentrations listed in the table below, with a 10 minute contact time in the presence of 400 ppm hard water and organic soil. Apply as directed under General One Step Disinfection and Cleaning Directions.

Virus	Concentration
[Feline Calicivirus]	[0.42 – 0.52 lbs. per gallon of water [50 – 63 grams/liter]]
[Norovirus]	[0.42 – 0.52 lbs. per gallon of water [50 – 63 grams/liter]]
[Rotavirus]	[0.42 – 0.52 lbs. per gallon of water [50 – 63 grams/liter]]

PED Virus

Preclean surfaces per the Precleaning Instructions. **Sterilex Ultra Powder** is effective against Porcine Epidemic Diarrhea Virus (PEDv) on hard, inanimate surfaces at 0.42-0.52 lbs Sterilex Ultra Powder per gallon of water [50 – 63 grams/liter], with a 10 minute contact time in the presence of 400 ppm hard water. Remove gross filth [soil] from all areas, articles and surfaces to be disinfected using a pre-clean, pre-flush, or pre-scrape and, if necessary, presoak. Mix 0.42-0.52 lbs Sterilex Ultra Powder per gallon of water [50 – 63 grams/liter]. Thoroughly wet surfaces by pouring, wiping, brushing, scrubbing, foaming, spraying with a coarse trigger sprayer, sponging, using a clean in place (CIP) system, pumping it through the system, drawing it through the system or mopping. Allow surfaces to remain wet for at least 10 minutes. Do not breathe spray. Rinse all surfaces thoroughly with a potable water rinse. Use within 8 hours after powder has been dissolved in water.

GENERAL SANITIZATION DIRECTIONS

Sterilex Ultra Powder eliminates 99.9% of the following bacteria in 5 minutes according to the Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces:

[Enterobacter aerogenese [ATCC 13048]]
[Staphylococcus aureus [ATCC 6538]]
[Escherichia coli [ATCC 11229] /
[Listeria monocytogenes [ATCC 49594]]
[Salmonella enterica [ATCC 10708]]

SANITIZING DIRECTIONS FOR NON-FOOD CONTACT SURFACES

Add a solution of 0.93 – 2 ounces Sterilex Ultra Powder per gallon of water [7 - 15 grams/liter] (or equivalent use dilution) to sanitize hard, non-porous surfaces. Apply sanitizer use solution to pre-cleaned, hard, non-porous surfaces with a cloth, mop, sponge, sprayer, foaming or by immersion. For sprayer applications, use a coarse pump or trigger sprayer. Spray 6-9 inches [15-22 cm] from surface. Do not breathe spray. Treated surfaces must remain wet for 5 minutes, then wipe with sponge, mop or cloth or allow to air dry. Use within 8 hours after powder has been dissolved in water.

[For food processing or other facilities that have installed entryway sanitizing systems.]

ENTRYWAY SANITIZING SYSTEMS:

To prevent cross contamination on treated surfaces, set the entryway system to apply a solution of 0.93 – 2 ounces Sterilex Ultra Powder per gallon of water [7 - 15 grams/liter] (or equivalent use dilution). The entire doorway path must be covered with the [spray] [foam] [footbath]. Ensure a continuous wet blanket of sanitizer solution is delivered to the [floor] [bath]. Use within 8 hours after powder has been dissolved in water.

SANITIZATION OF HARD, NON-POROUS (INANIMATE) (ENVIRONMENTAL) SURFACES ON [(PERSONAL PROTECTIVE EQUIPMENT) (PPE)]:

[Add] [Mix] 0.93 – 2 ounces Sterilex Ultra Powder per gallon of water [7 - 15 grams/liter] (or equivalent use dilution). Gently mix for uniform solution. Apply solution to hard, non-porous [inanimate] [environmental] surfaces of the [Personal Protective Equipment] [PPE] with a brush, cloth, mop, sponge, auto scrubber, mechanical spray device, foam or by immersion. Thoroughly wet all surfaces to be sanitized. Treated surfaces must remain wet for five (5) minutes. Remove excess solution from equipment prior to storage. Change cloth, sponge or towels frequently to avoid redeposition of soil. [Change the solution] [A Fresh solution must be prepared] [Prepare a fresh solution] at least daily or [more often if use solution] [when solution appears] becomes visibly [dirty] [soiled] [diluted].

SHOE FOAM DIRECTIONS:

Apply a foam layer that is approximately 0.5 to 2 inches [1.2 cm to 5 cm] thick at all entrances using a foam generating machine or aerator and a solution containing 0.93 – 2 ounces Sterilex Ultra Powder per gallon of water [7 - 15 grams/liter] (or equivalent use dilution). Scrape waterproof shoes and boots. Walk through foamed. Boots must remain wet for at least 5 minutes prior to entering area. Foamed entranceways must be washed and the foam replaced at least daily or when it foam/area appears dirty. Foam should be applied to entrances of buildings, hatcheries, production and packaging rooms to prevent cross contamination from area to area in the packaging and storage areas of food plants. Use within 8 hours after powder has been dissolved in water

APPLICATION INSTRUCTIONS FOR USE AS A [FLOOR SURFACE], [FLOOR MAT], [FOOT PAN] [BOOT] SANITIZER:

After cleaning and sanitizing equipment, [apply] [sprinkle] [spread] Sterilex Ultra Powder evenly to the [floor], [foot pan], [floor mat], [containment device], [and] [drain] surface, at a rate of 3.7- 7.4 oz. [105 - 210 grams] per 100 square feet of floor surface containing 1.3 fl. oz. – 5.1 fl. oz. [38 ml – 150 ml] of water per square foot. Product may be re-applied as needed during the production process. Sterilex Ultra Powder does not become active until it comes in contact with moisture.

Sterilex Ultra Powder has been evaluated at a concentration that supports a dilution of 0.93 ounces/gallon [7 grams/liter] in the presence of 5% soil contamination and in waters up to 500ppm hardness (29.2 gpg calculated as CaCO3). Treated surfaces must remain wet for 5 minutes.

Sterilex Ultra Powder was evaluated using the Non-Food Contact Surface Sanitizer Test and was proven to be effective against the following organisms:

[Staphylococcus aureus [ATCC 6538]] [Escherichia coli [ATCC 11229]] [Salmonella enterica [ATCC 10708]] [Enterobacter aerogenes [ATCC 13048]] [Listeria monocytogenes [ATCC 49594]]

DISINFECTION IN HOSPITALS, MEDICAL OFFICES, DENTAL OFFICES, DENTAL OPERATORIES, NURSING HOMES AND OTHER HUMAN HEALTH CARE FACILITIES:

NOTE:

This product is not to be used as a terminal sterilant/high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high-level disinfection.

APPLICATION INSTRUCTIONS:

- 1) Add 0.42 0.52 lbs. of **Sterilex Ultra Powder** to 1 gal. tap water [50 63 g of Sterilex Ultra Powder] to 1 liter tap water] in an appropriate plastic container and stir. Be sure all powder is dissolved.
- 2) Thoroughly wet surfaces with use-solution by pouring, wiping, brushing, scrubbing, foaming, spraying with a coarse trigger sprayer, sponging, using a clean in place (CIP) system, pumping it through the system, drawing it through the system or mopping.
- 3) Allow surfaces to remain wet for at least 10 minutes
- 4) Rinse all surfaces thoroughly with a potable water rinse.

Use product within 8 hours after powder has been dissolved in water.

INSTRUMENT PRE-SOAK:

For use as an instrument pre-soak, prepare a solution by adding 0.42-0.52 lbs. of **Sterilex Ultra Powder** to 1 gal. tap water [50-63 g of **Sterilex Ultra Powder** to 1 liter tap water] in an appropriate plastic container and stir. Immerse instruments completely and allow to soak for 10 minutes. Rinse all surfaces thoroughly with a potable water rinse. Instruments must undergo high-level disinfection or sterilization following presoak treatment. Use product within 8 hours after powder has been dissolved in water.

DISINFECTION IN ULTRASONIC BATHS:

NOTE:

Use **Sterilex Ultra Powder** to disinfect hard nonporous non-critical objects compatible with Ultrasonic Cleaning Units.

APPLICATION INSTRUCTIONS:

- 1) Pre-clean heavily soiled objects following the PRECLEANING INSTRUCTIONS on this label.
- 2) Add 0.42 0.52 lbs. of **Sterilex Ultra Powder** to 1 gal. tap water [50 63 g of **Sterilex Ultra Powder** to 1 liter tap water] in an appropriate plastic container and stir.
- 3) Pour fresh use-solution directly into bath chamber.
- 4) Place objects into unit and operate for a minimum of 10 minutes, according to the manufacturer's directions
- 5) Remove objects and wash with sterile water (sterile water for injection) and allow to air dry.
- 6) Prepare fresh solution for each use.

Use product within 8 hours after powder has been dissolved in water.

DISINFECTION AND SANITIZATION OF NON-FOOD CONTACT SURFACES OF FOOD PROCESSING EQUIPMENT AND HARD SURFACES IN FOOD PROCESSING FACILITIES, BREWERIES, WINERIES AND OTHER BEVERAGE MANUFACTURING FACILITIES, RESTAURANTS, BARS, CAFETERIAS, INSTITUTIONAL KITCHENS, CONVENIENCE STORES FOOD PREPARATION AREAS, FOOD STORAGE AREAS AND FOOD SERVICE AREAS:

NOTE:

Before use in federally inspected meat and poultry food processing plants and dairies, food products and packaging materials must be removed from the room or carefully protected. Follow all applicable local health and sanitation codes for sanitizing food processing equipment post-disinfection.

Apply **Sterilex Ultra Powder** as a disinfectant, per General One Step Disinfection and Cleaning Directions, or as a sanitizer, per General Sanitization Directions. Optionally, preclean surfaces per the Precleaning Instructions. Use product within 8 hours after powder has been dissolved in water.

DISINFECTION AND SANITIZATION OF NON-FOOD CONTACT SURFACES OF VETERINARY FACILITIES, ANIMAL CARE FACILITIES, ANIMAL LABORATORIES, ZOOS, PET SHOPS, KENNELS AND ANIMAL QUARTERS, FARM AND DAIRY FARM PREMISES, SWINE PREMISES, FARM AND DAIRY FARM PREMISE EQUIPMENT, SWINE PREMISE EQUIPMENT AND HATCHERIES.

Remove all animals and feed from premises, vehicles, and enclosures. Remove all litter and manure from floors, walls and surfaces of barns, pens, stalls, chutes, and other facilities and fixtures occupied or traversed by animals. Empty all troughs, racks, and other feeding and watering appliances. Thoroughly clean all surfaces with soap or detergent and rinse with water. Optionally, preclean surfaces per the Precleaning Instructions. Saturate all surfaces with the Sterilex Ultra Powder solution applied as a disinfectant, per General One Step Disinfection and Cleaning Directions, or as a sanitizer, per General Sanitization Directions. Immerse all halters, ropes, and other types of equipment used in handling and restraining animals, as well as forks, shovels, and scrapers used for removing litter and manure. Ventilate buildings, cars, boats, and other closed spaces. Do not house livestock or employ equipment until treatment has been absorbed, set, or dried. Thoroughly scrub all treated feed racks, mangers, troughs, automatic feeders, fountains, and waterers with soap or detergent, and rinse with potable water before reuse.

Use product within 8 hours after powder has been dissolved in water.

DISINFECTION AND SANITIZATION OF NON-FOOD CONTACT SURFACES OF POULTRY PREMISES, POULTRY PREMISE EQUIPMENT AND HATCHERIES

Remove all poultry and feeds from premises, trucks, coops, and crates. Remove all litter and droppings from floors, walls and surfaces of facilities occupied or traversed by poultry. Empty all troughs, racks, and other feeding and watering appliances. Thoroughly clean all surfaces with soap or detergent and rinse with water. Optionally, preclean surfaces per the Precleaning Instructions. Saturate surfaces with the Sterilex Ultra Powder solution applied as a disinfectant, per General One Step Disinfection and Cleaning Directions, or as a sanitizer, per General Sanitization Directions. Ventilate buildings, coops, and other closed spaces. Do not house poultry or employ equipment until treatment has been absorbed, set, or dried. Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains, and waterers with soap or detergent, and rinse with potable water before reuse.

Use product within 8 hours after powder has been dissolved in water.

CLEANING AND DISINFECTION OF ANIMAL DRINKING LINES:

This product can be used to clean and disinfect tanks, pumps or medicators used to deliver the product, piping and tubing associated with water lines in animal, livestock and poultry housing facilities. The water lines can be used for delivering drinking water, air chiller water and cooling spray lines. Prior to use in the water lines, remove all animals, livestock or birds from premises. Do not reintroduce animals, livestock or birds until treatment is complete and water lines have been thoroughly rinsed with potable water.

Ensure all animals are removed from the farm. Apply disinfecting solution to the lines by adding 0.42 - 0.52 lbs. per gallon of water [50 - 62.5 grams/L] to the drinking water system. Fill the system by using a clean in place (CIP) system, pumping it through the system, or drawing it through the system. Make sure there is enough solution to fill the lines. Trigger all drinkers to ensure solution flows over the nipple. If a drinker is not working, continue to trigger it until water flows freely. Allow surfaces to remain wet for at least 10 minutes. Rinse all surfaces thoroughly with a potable water rinse.

Use product within 8 hours after powder has been dissolved in water.

SANITIZING ANIMAL DRINKING LINES:

This product can be used to sanitize tanks, pumps or medicators used to deliver the product, piping and tubing associated with water lines in animal, livestock and poultry housing facilities. The water lines can be used for delivering drinking water, air chiller water and cooling spray lines. Prior to use in the water lines, remove all animals, livestock or birds from premises. Do not reintroduce animals, livestock or birds until treatment is complete and water lines have been thoroughly rinsed with potable water.

Ensure all animals are removed from the farm. Apply sanitizing solution to the lines by adding 0.93 - 2 oz. per gallon of water [7 - 15 grams/L] to the drinking water system. Fill the system by using a clean in place (CIP) system, pumping it through the system, or drawing it through the system. Make sure there is enough solution to fill the lines. Trigger all drinkers to ensure solution flows over the nipple. If a drinker is not working, continue to trigger it until water flows freely. Allow surfaces to remain wet for at least 5 minutes. Rinse all surfaces thoroughly with a potable water rinse.

Use product within 8 hours after powder has been dissolved in water.

SANITIZING DIRECTIONS FOR NON-FOOD CONTACT SURFACES INCLUDING EGG FLATS, TRUCKS, AND OTHER ENVIRONMENTAL SURFACES:

Add 0.93 – 2 oz. per gallon of water [7 – 15 grams/L] of **Sterilex Ultra Powder** to 1 gallon [3.78 L] of water (or equivalent use dilution) to sanitize hard, non-porous surfaces. Apply sanitizer use solution to precleaned, hard, non-porous surfaces with a cloth, mop, sponge, sprayer, foaming or by immersion. For sprayer applications, use a coarse pump or trigger sprayer. Spray 6-9 inches [15-22 cm] from surface. Do not breathe spray. Treated surfaces must remain wet for 5 minutes, then wipe with sponge, mop or cloth, rinse, or allow to air dry.

Use product within 8 hours after powder has been dissolved in water.

DISINFECTION AND SANITIZATION OF NON-FOOD CONTACT SURFACES IN REFRIGERATED TRUCKS AND OTHER VEHICLES, INSTITUTIONS, INDUSTRIAL FACILITIES, SCHOOLS, ATHLETIC FACILITIES, REST ROOMS, HOTELS, MOTELS, OFFICE BUILDINGS AND OTHER PUBLIC AREAS, AND HOUSEHOLDS:

Apply **Sterilex Ultra Powder** as a disinfectant, per General One Step Disinfection and Cleaning Directions, or as a sanitizer, per General Sanitization Directions. Optionally, preclean surfaces per the Precleaning Instructions. Use product within 8 hours after powder has been dissolved in water.

Use product within 8 hours after powder has been dissolved in water.

DISINFECTION OF SALON (BARBER) INSTRUMENTS AND TOOLS:

APPLICATION INSTRUCTIONS:

Add 0.42 lb. of **Sterilex Ultra Powder** to 1 gal. tap water [50 g of **Sterilex Ultra Powder** to 1 liter tap water] in an appropriate plastic container and stir. Completely immerse combs, brushes, plastic rollers, manicure and other hard, nonporous salon instruments and tools for 10 minutes. Allow surfaces to remain wet for at least 10 minutes. Rinse all thoroughly with potable water and dry before use. Fresh solution must be prepared daily or more often if solution becomes diluted or soiled.

Use product within 8 hours after powder has been dissolved in water.

NOTE:

Plastics may remain immersed until ready to use. Stainless steel shears and instruments must be removed after 10 minutes, rinsed, dried and kept in a clean, non-contaminated receptacle. Prolonged soaking may cause damage to metal instruments.

PRECLEANING OF WHIRLPOOL BATH, SPA AND JACUZZI TUB SURFACES:

Close the Whirlpool bath, Spa or Jacuzzi to bathers. Turn off/close all chemical treatment lines, sensors, chlorine (bromine) feeders and pH chemical adjusters. The amount of water to be treated equals the capacity in gallons of the Whirlpool batch, spa or Jacuzzi tub. Add 0.01 – 0.21 lbs. of **Sterilex Ultra Powder** in 1 gallon of water [1-25 g of **Sterilex Ultra Powder** to 1 liter water] to be treated. Briefly start the pump to circulate the solution. Turn off the pump. Wash down the sides, seat of the chair and any and all related equipment with a clean swab, sponge or brush. Drain solution from the unit and rinse cleaned surfaces and equipment with fresh water. Use product within 8 hours after powder has been dissolved in water.

CLEANING AND DISINFECTION OF WHIRLPOOL BATH, SPA AND JACUZZI TUB SURFACES:

NOTE: During treatment bathers must not enter the whirlpool, spa and Jacuzzi tubs.

Turn off/close all chemical treatment lines, sensors, chlorine (bromine) feeders and pH chemical adjusters. The amount of water to be treated equals the capacity in gallons of the Whirlpool bath, spa or Jacuzzi tub. Add 0.42-0.52 lbs of product per gallon of water [50-63] g of **Sterilex Ultra Powder** to 1 liter water] to be treated. Begin circulation of the product to assure even distribution of the product through the piping systems. Circulate the product for at least 10 minutes after the product has been evenly distributed through the piping system. Drain the entire system. Flush (rinse) the entire system by refilling the entire system with clean fresh water. Rinse all cleaned surfaces with fresh water.

Use product within 8 hours after powder has been dissolved in water.

PRECAUTIONARY STATEMENTS

Hazard To Humans And Domestic Animals.

DANGER. Corrosive. Causes irreversible eye damage and skin burns. Do not get in eyes, on skin, or on clothing. Harmful if swallowed or absorbed through skin. Wear protective eyewear (goggles and/or face shield), protective clothing and waterproof gloves. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove contaminated clothing and wash clothing before reuse.

WHEN POWDER IS DILUTED: Causes moderate eye irritation. Harmful if absorbed through skin or inhaled. Avoid breathing vapor. Avoid contact with eyes, skin or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove contaminated clothing and wash clothing before reuse.

FIRST AID

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. Call a poison control center or doctor for treatment advice.

IF ON SKIN: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

IF INHALED: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. Call a poison control center or doctor for further treatment advice.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

STORAGE AND DISPOSAL

PESTICIDE STORAGE: Keep out of children's reach. Store at room temperature out of direct sunlight, DO NOT store above 30°C (or 86°F).

PESTICIDE DISPOSAL: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL:

(NOTE TO REVIEWER: The following language is for the nonrefillable 0.44-ounce (12.5-gram) packet only) Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities. Completely empty packet into application equipment by shaking and tapping sides and bottom to loosen clinging particles. If not emptied in this manner, the packet may be considered an acute hazardous waste and must be disposed in accordance with local, state and federal regulations. When completely empty discard packet in trash.

(NOTE TO REVIEWER: The following language is for nonrefillable fiber drum with plastic liner bag containers having a capacity greater than 5 pounds) Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities. Completely empty bag into application equipment by shaking and tapping sides and bottom to loosen clinging particles. If not emptied in this manner, the bag may be considered an acute hazardous waste and must be disposed in accordance with local, state and federal regulations. When completely empty, offer for recycling if available or dispose of bag in a sanitary landfill or by incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

(NOTE TO REVIEWER: The following language is for <u>nonrefillable</u> rigid plastic containers with plastic liner bag containers having a capacity of 10 pounds or less)

Nonrefillable container. Do not reuse or refill this container. Completely empty bag into application equipment by shaking and tapping sides and bottom to loosen clinging particles. If not emptied in this manner, the bag may be considered an acute hazardous waste and must be disposed in accordance with local, state and federal regulations. When completely empty, offer for recycling if available or dispose of bag in a sanitary landfill or by incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

(NOTE TO REVIEWER: The following language is optional for <u>nonrefillable</u> rigid plastic containers having a capacity of 10 pounds or more when "or pressure rinse" appears in the Container Disposal statement)

Nonrefillable container. [Triple rinse] [or] [pressure rinse container] (or equivalent) promptly after emptying. [Pressure rinse as follows: Insert pressure rinsing nozzle in the side of the container, and rinse at about 40 PSI for at least 30 seconds. Drain for 10 seconds after the flow begins to drip. Dispose of rinsate as pesticide waste. Do not reuse or refill this container. Offer for recycling, if available or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities. If rinsate cannot be used, follow pesticide disposal instructions. If not triple rinsed these containers are acute hazardous wastes and must be disposed in accordance with local, state and federal regulations.]

[Triple rinse as follows: Fill the container ¼ full with water and recap. Shake for 10 seconds. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Dispose of rinsate as pesticide waste. If rinsate cannot be used, follow pesticide disposal instructions. Offer for recycling, if available or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities. If not triple rinsed these containers are acute hazardous wastes and must be disposed in accordance with local, state and federal regulations.]